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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Squire, Sanders & Dempsey L.L.P.
Suite 300
One Maritime Plaza
San Francisco, CA 94111

EXAMINER

FOREMAN, JONATHAN M

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/967,186	Applicant(s) ELLIS ET AL.	
	Examiner Jonathan ML Foreman	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2005.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-5, 7-13 and 15-32 is/are rejected.
 7) ☒ Claim(s) 6 and 14 is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1 - 5, 17, 19, 20, 21, 24 and 26 – 28 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,498,941 to Jackson.

In regards to claims 1 - 5, 17, 19, 20, 21, 24 and 26 – 28, Jackson discloses an elongated wire assembly (Figure 4B) in that the catheter disclosed by Jackson resembles a wire, as in slenderness or stiffness (<http://dictionary.reference.com/search?q=wire>). The elongated wire assembly is capable of being guided to a designated region of a vessel (53) within a patient's body (Col. 3, lines 11 – 12), the assembly comprising an elongated member including a lumen (Col. 5, lines 23 – 25) disposed along a segment of the member, and an opening in the elongated member, the opening positioned so that the lumen is in fluid communication with the vessel (Figure 4B); and a sensor positioned within the lumen of the elongated member so that the sensor is in fluid communication with the vessel through the opening (Col. 5, lines 28 – 33), the sensor being capable of measuring the level of nitric oxide or superoxide molecules in the vessel of the patient's body (Col. 2, lines 39 – 67; Col. 3, lines 5 – 10), wherein the sensor is capable of being moved independently of a distal end of the elongated member for adjusting the position of the sensor relative to the distal end (Col. 5, lines 28 – 33). A catheter is capable of being slidably disposed over a portion of the assemble. The sensor

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includes a compound that can react with nitric oxide or superoxide leading to a change in the optical properties of the compound (Col. 6, lines 39 – 51); and an optical system capable of measuring the optical properties of the compound change (Figure 1A). Jackson discloses a first (15a) and second (15b) fiber optic line. The sensor includes a sensor tip capable of independently bending away from, being slidably along and rotatably about a central longitudinal axis of the elongated member (Col. 5, lines 28 – 33). It has been held that the recitation that an element is “capable of” performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,498,941 to Jackson in view of U.S. Patent No. 5,582,170 to Soller.

In regards to claim 7, Jackson discloses the sensor being capable of detecting a desired chemical or analyte (Col. 3, lines 7 – 10), but fail to disclose the desired chemical or analyte being nitric oxide or superoxide. However, Soller teaches an elongated assembly and a method using the elongated assembly comprising: positioning the elongated assembly into a designated region within a blood vessel (Col. 11, lines 16 – 19) and measuring the level of nitric oxide (NO) in the region of the vessel (Col. 11, line 20) using a sensor including a catalytic material capable of oxidizing NO (Col. 10, lines 23 – 44) in order to change optical properties of the compound. It would have been

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obvious to one having ordinary skill in the art at the time the invention was made to modify the device and method as disclosed by Jackson to include a compound capable of oxidizing NO or superoxide as taught by Soller to measure NO or superoxide in a vessel.

5. Claims 8, 9, 13, 15, 16, 18, 22, 23, 25 and 29 – 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,498,941 to Jackson in view of U.S. Patent No. 5,582,170 to Soller.

In regards to claims 8, 9, 13, 15, 16, 18, 22, 23, 25 and 29 – 32, Jackson discloses a method for measuring the level of a chemical or analyte in a vessel including positing an elongated wire assembly in a vessel (53) within a patient's body (Col. 3, lines 11 – 12) to a designated region within the vessel affected by thrombosis or restenosis (Col. 5, lines 1 – 5), the assembly comprising an elongated member including a lumen (Col. 5, lines 23 – 25) disposed along a segment of the member, and an opening in the elongated member, the opening positioned so that the lumen is in fluid communication with the vessel (Figure 4B); and a sensor positioned within the lumen of the elongated member so that the sensor is in fluid communication with the vessel through the opening (Col. 5, lines 28 – 33), wherein the sensor is capable of being moved independently of a distal end of the elongated member for adjusting the position of the sensor relative to the distal end (Col. 5, lines 28 – 33). Jackson discloses the sensor includes a variety of compounds that can react with a desired chemical or analyte to a change in the optical properties of the compound (Col. 6, lines 39 – 51); and an optical system capable of measuring the optical properties of the compound change (Figure 1A). Jackson discloses a first (15a) and second (15b) fiber optic line. The sensor includes a sensor tip capable of independently bending away from, being slidably along and rotatably about a central longitudinal axis of the elongated member (Col. 5, lines 28 – 33). Jackson discloses the sensor being capable of detecting a desired chemical or analyte (Col. 3, lines 7 – 10), but fail to disclose the

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desired chemical or analyte being nitric oxide or superoxide. However, Soller teaches an elongated assembly and a method using the elongated assembly comprising: positioning the elongated assembly into a designated region within a blood vessel (Col. 11, lines 16 – 19) and measuring the level of nitric oxide (NO) in the region of the vessel (Col. 11, line 20) using a sensor including a catalytic material capable of oxidizing NO (Col. 10, lines 23 – 44) in order to change optical properties of the compound. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device and method as disclosed by Jackson to include a compound capable of oxidizing NO or superoxide as taught by Soller to measure NO or superoxide in a vessel.

6. Claims 10, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,498,941 to Jackson in view of U.S. Patent No. 5,582,170 to Soller as applied to claim 8 above, and further in view of U.S. Patent No. 5,945,542 to Cooke et al.

In reference to claims 10, 11 and 12, the method as disclosed by Jackson in view of Soller as discussed above fails to disclose the steps of inserting a catheter over the wire assembly, delivering the stimulant acetylcholine, and the designated region within the vessel being affected by restenosis. Cooke et al. discloses a method wherein an infusion catheter is advanced over a guide wire to infuse acetylcholine (Col. 18, lines 35 – 38). Cooke et al. teaches that administering acetylcholine diminishes the formation of atherosclerotic plaque and restenosis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Jackson in view of Soller to include the steps of advancing a catheter over the guidewire to administer the stimulant acetylcholine to an area of restenosis in a vessel as taught by Cooke et al. in order to diminish the formation of atherosclerotic plaque and restenosis by inhibiting adhesion

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of monocytes and platelets, and by reducing the proliferation of vascular smooth muscle cells (Col. 18, line 63 – Col. 19, line 3).

Response to Arguments

7. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

8. Claims 6 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JMLF



MAX HINDENBURG

SENIOR PATENT EXAMINER

TECHNOLOGY CENTER 3700